Advocacy for ratification

Arthur Dani Hzizidi examines slides for malaria parasites at the Institut National de Recherche Biologique (INRB) in Kinshasa, DRC. With PATH/MalariaCARE support, the INRB is helping to build a national archive of malaria slides. Photo: PATH/Georgina Goodwin.

Africa's pharmaceutical industry has undergone tremendous growth in all sectors over the years. This growth can be attributed to improvements in infrastructure, health care capacity, and business environment. The COVID-19 pandemic, however, brought to light the critical need for a more structured, robust, and resilient manufacturing sector for the continent. The industry was pushed by crisis to pick up the pace at establishing harmony within its different sectors, ensuring that they largely serve the African people and reduce over-reliance on pharmaceutical imports. This crisis also prompted increased political support for local medical products manufacturing, leading to a substantial expansion of African pharmaceutical manufacturing.
National Regulatory Authorities (NRAs) are responsible for ensuring that products released for public distribution (normally pharmaceuticals and biological products, including vaccines, medical devices, and test kits) are evaluated properly and meet international standards of quality, safety, and efficacy. NRAs have been established in most African countries, but they vary in their functionalities, growth stages, and expertise levels. Some carry out regulatory functions as mandated by their Ministry of Health (MOH), while others are completely independent of the MOH. These NRAs are mandated to regulate medical products and have the priority to facilitate public access to these products despite facing different constraints.

The African Medicines Agency (AMA) Treaty, adopted in 2019, was mandated to enhance the approval process for safe and high-quality medical products by facilitating collaboration and reliance mechanisms. It provides regulatory and scientific guidance for priority diseases, emerging diseases, and traditional medicines. AMA aims to harmonize regulatory frameworks across Africa, promote local production, stimulate innovation, and ensure the efficient introduction of innovations to the African market. It builds upon the African Medicines Regulatory Harmonization initiative and is the second specialized health agency of the African Union, after the Africa Centres for Disease Control and Prevention.

AMA will ensure regulatory convergence and reliance, which promotes faster introduction of new and advanced medical products into the market, hence quicker access by patients at a lower cost because the final cost of accessing medical products is a composite of time taken and fees paid during regulation of such products.

—Johnpaul Omollo, PATH, Regional Lead, Research and Development Policy and Advocacy

Only 27 out of 55 African countries have ratified the treaty and deposited their written instruments of ratification (which provide formal evidence of consent to be bound by the treaty and may include reservations and declarations) as of March 2024. This slow process delays the intention to harmonize and strengthen regulatory systems at a continental level.

Challenges

For over five years, PATH has been working with the policymakers in Kenya, and South Africa, as well as other countries, offering technical support and advocacy for ratification of the treaty. From experience, we realized that some of the factors contributing to the delay in treaty ratification include the following.

Long and unclear process of ratification

While countries are required to sign and later officially ratify the treaty in their parliaments for it to become applicable, the legal ratification process varies across different countries. This process can be slowed down by inadequate information about the AMA and a lack of understanding by stakeholders about the processes of ratification and depositing written instruments—processes that differ in each country. Additionally, there are low and varying levels of understanding of the difference between signing the treaty and full treaty ratification at the country level. For some countries, NRAs have taken the lead in pushing concerned authorities to ratify the treaty, while for other countries, the ministries of health, ministries of foreign affairs, or even heads of state are entirely in charge of the process.
Ambiguity on the role of the AMA as it relates to the NRAs

The role of the AMA is considered ambiguous by some countries and NRAs, and questions have been raised about whether the agency will take over the role of the NRAs or duplicate their efforts. Some NRAs are already members of Regional Economic Communities, and there is concern that the already limited NRA staff may be required to provide their regulatory harmonization expertise at national, regional, and continental levels. There is also fear that the AMA may take over NRA responsibilities and even expropriate their fees, which NRAs currently charge for product evaluation. These concerns are a major contributor to the apprehension and delays around treaty ratification, especially in countries where the NRA is meant to take a leadership role in driving the ratification process.

Limited financial resources

The AMA requires sustainable financing mechanisms from countries to implement its functions. African governments are currently constrained to meet their health financing targets, with economic unpredictability and competing financing needs. The added need for contributions to the AMA is an extra cost for countries with an already overstretched budget, especially when member states are also unable to clearly attribute a return on their investment when it comes to how the AMA will financially contribute to cushioning them. It can be difficult for some to see, in the urgency of the short term, the advantages of a long-term investment.

At the country level, the lack of adequate resources for policy and legislative processes inhibits treaty ratification because most NRAs do not have enough financial power to support these processes. Inadequate financing further affects the strengthening of NRAs and raises concerns about whether, once operational, the AMA will prioritize countries with greater regulatory capacity.

Political landscape

Changes in the political environment, such as competing government policy priorities, elections, and government staff changes, have delayed treaty ratification. With changes in office, there is a need to
also build political goodwill with new administrators to hasten the legislation process. This, coupled with bureaucracy in some countries, has slowed down the ratification process.

Interventions

Besides providing technical support to countries, PATH has further worked with the African Union Development Agency–New Partnership for Africa's Development (AUDA-NEPAD) to develop a training manual on the legal steps for AMA Treaty ratification and African Union (AU) Model Law, as well as communication packets with information defining the role of the AMA and its relationship with the NRAs. PATH also supported civil society groups, AMA advocates, and NRAs, among other stakeholders, in engagements to understand the process of treaty ratification.

In Kenya, Tanzania, and South Africa, PATH contributed to the ratification of the AMA Treaty by providing continuous technical support through written technical brief materials, presentations, and interactive sessions for decision-makers, emphasizing the importance of the agency's process and benefits for the country and the continent. PATH also involved government stakeholders as advocates for ratification, entrusting them with mobilizing support for the AMA at the highest policymaking levels. Additionally, we played a pivotal role in leading civil society efforts by issuing a call to action urging members of parliament to prioritize the ratification process.

PATH organized dialogues at regional and international conferences to promote the vision of the AMA and stimulate discussions among sector leaders. Recently, in South Africa, PATH collaborated with the South African Health Products Regulatory Authority, AUDA-NEPAD, and the media to convene cross-sectoral stakeholders for a meeting, celebrating the milestones achieved by the national
regulator and advocating further for ratification of the AMA Treaty. These efforts by PATH have seen Kenya and Tanzania ratify the treaty in 2023. PATH is currently providing similar support to the governments of Nigeria and South Africa toward full ratification of the treaty.

**Lessons learned**

**NRA involvement**

NRA involvement in the AMA Treaty’s ratification is key. Having an established NRA is an important enabling factor for the signing of the treaty by an AU member state, as well as having a robust regulatory system. In Kenya and South Africa, the NRAs led the process of ratification, following up on documentation with the ministries of health, leading dialogues, and hosting stakeholder engagements on the ratification process. The NRAs provided crucial advisory support to the ministries of health and parliamentary committees in the process of ratification. NRAs in Kenya and South Africa led advocacy efforts with their leadership, writing media articles about the AMA and working with institutions like PATH and AUDA-NEPAD to convince their governments to sign and ratify the treaty.

The African Medicines Regulatory Harmonisation (AMRH) program is playing a critical role in building the foundation for AMA. Through our established continental working committees, we are building the technical capacity for reliance and collaboration needed to implement AMA and advance regulatory efficiencies on the continent. We are committed to improving the health and wellbeing of Africans by prioritizing the safety and efficacy of medical products on the continent.

— Chimwemwe Chamdimba, Head of AMRH, AUDA-NEPAD

**Multisectoral stakeholder advocacy**

Multisectoral stakeholder advocacy is instrumental in achieving ratification. In Kenya and South Africa, NRAs and PATH worked with various stakeholders to advocate for treaty ratification up to the ministerial level. The process was hastened by cultivating internal advocates within the NRAs and the ministries of health, as well as external advocates—including civil society groups, pharmaceutical societies and manufacturers, the media, Regional Economic Committees, and international institutions, such as the AU and the World Health Organization. PATH held different engagement meetings with the NRAs that provided opportunities for them to advocate for treaty ratification with stakeholders in Kenya and South Africa. The different methods of engaging these stakeholders included meetings, training, and informal and formal discussions during conferences and convenings.

**Political goodwill for regulatory harmonization**

Strong political goodwill and the prioritization by the government and the ministries of health in Kenya, Tanzania, and South Africa helped to speed up the ratification of the treaty. Political goodwill is created when powerful decision-makers with legal and financial influence understand the importance and benefits of strengthened NRAs, harmonized regulatory systems, and the role the AMA plays in reaching these goals. Advocacy engagements are an invaluable component. In Kenya and South Africa, PATH developed communication packages to share information, equipping leadership with the information they needed when making decisions during the treaty ratification process. PATH is also providing Kenya with technical support on the legislation of the Kenya Drugs Authority Bill that will see the establishment of a strengthened drug authority for the country and contribute toward the country’s NRA achieving maturity level 3 status.
Commitment to financing

An obligatory prerequisite for countries that have ratified the treaty is the commitment of resources to cofinance the operations of the AMA. Member states will be required to commit financial, technical, and in-kind resources to support the operationalization and administration of the agency; these resources will not only strengthen clinical trials and improve manufacturing standards within each country but also position regulatory bodies in the continent on a global scale.

Aligning country and continental regulatory frameworks

For the AMA to function effectively and efficiently, countries need to align with the continent’s regulatory law, the AU Model Law for medical products regulation, and the AMA’s health care policies. AMA member countries will also be required to create a conducive environment for the sustainability of the pharmaceutical industry to encourage local pharmaceutical production, in line with the Pharmaceutical Manufacturing Plan for Africa and its business plan. Policy coherence across government ministries relevant and related to the pharmaceutical industry, alongside the AMA, will be key to the success of local pharmaceutical production in the continent.

PATH recognizes that regional collaborations are vital for the growth of individual countries, regions, and the continent at large. The quest to provide universal health coverage by most of the member countries will only be achieved through close continental collaboration. The AMA provides an assurance of safe, effective, and efficacious medical products circulating within the African markets. It will also ensure quality of care received by Africans across the continent.

—Dr. Nanthalile Mugala, PATH’s Chief of Africa Region

Looking forward

PATH continues to be a strong partner to the AUDA-NEPAD to support ratification and operationalization of AMA. Together, we engage in vital dialogues with influential figures across the African continent, including heads of state, ministers, and policy experts. Through these partnerships, we have allocated resources to support working groups, offered guidance in advocacy strategy development, and enhanced the visibility of progress being made. This collective effort will continue to emphasize the urgent need for the ratification of the AMA Treaty by all 55 AU member states, and the necessary steps to begin operationalizing this important agency.